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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,586	10/17/2001	George A. Gaitanaris	50001/002005	7567

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BOSTON, MA 02110

EXAMINER

QIAN, CELINE X

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 03/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

8.14

Office Action Summary

Application No.

09/982,586

Applicant(s)

GAITANARIS, GEORGE A.31 C

Examiner

Celine X Qian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 15-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/17/01 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/17/01.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Claims 1-18 are pending in the application. Claims 15-17 are withdrawn from consideration for being directed to a non-elected subject matter.

This Office Action is in response to the Amendment filed on 12/29/03.

Response to Amendment

The objection to the Oath and Declaration has been withdrawn in light of Applicant's persuasive argument.

The rejection of claims 5-7 under 35 U.S.C. 112 2nd paragraph has been withdrawn in light of Applicant's amendment of the claims.

Claims 1-14 and newly added claim 18 stand rejected under 35 U.S.C. 112 1st paragraph for reasons set forth of the record mailed on 7/2/03 and further discussed below.

Claims 1-14 and newly added claim 18 stand rejected under 35 U.S.C. 103 (a) for reasons set forth of the record mailed on 7/2/03 and further discussed below.

Claims 5-7 are rejected under 35 U.S.C. 112 2nd paragraph for reasons set forth below.

Response to Arguments

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14 and newly added claim 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter

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which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In response to this rejection, applicants argue that many lines (3 out of 6) of transgenic mice comprising the recited transgene have a readily identifiable phenotype. Applicants also argue that the specification does teach how to use the claimed mice regardless of whether there is a readily identifiable phenotype, including use of the mice to mate with mice containing a marker gene under the control of the rtTA-dependent promoter to produce offspring carrying marker only when cells express rtTA in the presence of tetracycline derivative, conditional ablation of cell lineages expressing mutant genes, the spatio-temporal phenotypic analysis of disrupted genes, and conditional expression of genes of interest. Applicants therefore conclude that the claimed invention is enabled to its full scope.

These arguments have been fully considered but deemed unpersuasive. The detailed reason for the non-enablement of the claimed inventions was discussed in detail mailed on 7/2/03. In response to Applicant's argument in regard with the transgene dependent phenotype, it is reminded that the specification does not teach that the claimed mice have any readily identifiable phenotype, or what type of phenotype these mice exhibit. The instant specification has to provide teaching on such phenotype to support the enablement of the invention. In addition, regarding use of the mice to mate with mice containing a marker gene under the control of the rtTA-dependent promoter and produce offspring carrying marker only when cells expressing rtTA in the presence of tetracycline derivative, conditional ablation of cell lineages expressing mutant genes, the spatio-temporal phenotypic analysis of disrupted genes, and conditional expression of genes of interest, it requires that the mice comprising said regulatory

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transgene, for example rtTA, been expressed at sufficient level so that the expression of the gene of interest is regulated by said transgene under desirable condition (in the presence of tetracycline derivatives). A retroviral vector integrates into the host genome randomly. As such, whether the resulting mouse would express the regulatory transgene at such level is unpredictable. The specification does not teach how to use a mouse without expression of the transgene or other types of phenotype. Therefore, one of skilled in the art would have to engage in undue experimentation to practice the invention. Thus, the claimed invention is not enabled by the instant specification.

The newly added claim 18 is rejected for same reasons as discussed in the previous office action and above.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-8 and 14 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Friedrich et al. (IDS), in view of St-Onge et al (1996, Nucleic Acid Research, Vol.24, No.19, pp.3875-3877).

Claims 9-12 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Friedrich et al., in view of St-Onge et al. as applied to claims 1-8 and 14 above, and further in view of Zhang et al (1996, BBRC, vol.227, pages 707-711).

Claim 13 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Friedrich et al., in view of St-Onge et al. as applied to claims 1-8 and 14 above, and further in view of Bremer et al.

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In response to this rejection, Applicants argue that the cited references fail to provide every limitation of the claimed invention, namely, a transcription terminator. Applicants thus conclude that the invention is not obvious in view of the cited references.

This argument have been fully considered but deemed unpersuasive. The detailed reasons for obviousness of the claimed invention in view of the cited references were discussed in detail in the office action mailed on 7/2/03. In response to above argument, Applicant's attention is directed to page 6, 1st paragraph of the previous office action. The limitation of a transcriptional terminator is taught by St-Onge et al (see page 3875, 1st col., 1st paragraph and Figure 1 of the reference). Therefore, the combined references teach every limitation of the claimed invention, and the invention is obvious.

New Grounds of Rejection Necessitated by Applicant's Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5-7 recite the limitation "a second transgene." There is insufficient antecedent basis for this limitation in the claim. The parent claim (1) only recites one transgene.

Conclusion

No claims are allowed.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine Qian, Ph.D.

Anne-Marie Falk
ANNE-MARIE FALK, PH.D.
PRIMARY EXAMINER